Exhibit A

SETTLEMENT AGREEMENT AND RELEASE

I. PARTIES

This Settlement Agreement ("Agreement") is entered into on behalf of the United States of America by Ven-A-Care of the Florida Keys, Inc. (the "Relator"); the attorneys for the Relator; the State of California ("California"); the State of Florida ("Florida"); and Schering-Plough Corporation ("Schering-Plough"), Schering Corporation ("Schering"), and Warrick Pharmaceuticals Corporation ("Warrick") (collectively, "Schering/Warrick"). Collectively, all of the above will be referred to as "the Parties."

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

- A. At all relevant times, Schering-Plough Corporation was a New Jersey corporation headquartered in Kenilworth, New Jersey.
- B. At all relevant times, Schering Corporation, a New Jersey corporation and wholly-owned subsidiary of Schering-Plough Corporation, manufactured, marketed, and sold branded pharmaceutical products in the United States.
- C. At all relevant times, Warrick Pharmaceuticals Corporation, a Delaware corporation and wholly-owned subsidiary of Schering, marketed and sold generic pharmaceutical products in the United States.
- D. Ven-A-Care of the Florida Keys, Inc. is a corporation with its principal place of business in Key West, Florida. Zachary T. Bentley, T. Mark Jones, John M. Lockwood, and Luis E. Cobo are or were officers and directors of Ven-A-Care of the Florida Keys, Inc. and, in such capacity took action to cause the corporation, as the Relator, to bring the qui tam actions specified in II E

- E. On or about June 23, 1995, Ven-A-Care of the Florida Keys, Inc. filed a qui tam action in the United States District Court for the Southern District of Florida captioned United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Bristol Myers Squibb Co., et al., Civil Action No. 95-1354 (S.D. Fla.) (the "Florida Civil Action"). That complaint was subsequently amended to add claims against Schering/Warrick. On or about January 5, 2009, the claims asserted in the Florida Civil Action against Schering/Warrick were severed, and the Relator filed a further Amended Complaint in the Southern District of Florida under the caption *United States* ex rel Ven-A-care of the Florida Keys, Inc. v. Schering Corporation et al., Civil Action No. 09-10003 (S.D. Fla.)(the "Second Florida Civil Action"). On or about April 10, 2000, Ven-A-Care filed another qui tam action in the United States District Court for the District of Massachusetts captioned United States ex rel Ven-A-Care of the Florida Keys, Inc. v. Apothecon et al., Civil Action No. 00-10698 (D. Mass.) (the "Massachusetts Civil Action") (together, the "Civil Actions"). On or about December 16, 2008, the claims asserted in the Massachusetts Civil Action against Schering/Warrick were severed, and the Relator filed an Amended Complaint in the same court under the same caption and case number that included as defendants only Schering-Plough Corporation, Schering Corporation, and Warrick Pharmaceuticals Corporation. The Civil Actions have been transferred to MDL 1456 before the Honorable Patti B. Saris of the United States District Court for the District of Massachusetts.
- F. The Relator on behalf of the United States contends that Schering and Warrick submitted, or caused to be submitted, false claims to the Medicaid Program. As a result, the Relator contends that the United States has certain claims against Schering/Warrick for engaging in the following conduct (hereinafter the "Covered Conduct"). Specifically, the Relator on behalf of the United States contends that, during the period from January 1, 1991 through the

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date that this Agreement is executed by all parties (the "Relevant Period"), Schering/Warrick knowingly set, reported, and maintained or caused to be set, reported and maintained false, fraudulent, and inflated Average Wholesale Prices, Suggested List Prices, Wholesale Acquisition Costs, Wholesale Net Prices, Direct Prices, Wholesale Direct Prices, and Net Direct Prices, among others, (the "Reported Prices") for all drugs manufactured, marketed, or sold by Labeler 59930 (the "Warrick Covered Drugs"). These reported prices were higher, and sometimes substantially higher, than the prices paid by Schering/Warrick's customers for certain of the Warrick Covered Drugs. Schering/Warrick allegedly used the artificially inflated spread between the Reported Prices and the actual selling prices for these drugs in marketing, promoting, and selling drugs to existing and potential customers. Schering/Warrick allegedly knew that the reporting of false, fraudulent, and inflated Reported Prices in connection with certain drugs and/or marketing those drugs based on the artificially inflated spread between the Reported Prices and the actual selling prices would cause the customers and others to submit false, fraudulent, and excessive claims for reimbursement to the Medicaid Program.

- G. The Relator on behalf of the United States contends that the Medicaid Program was damaged as a result of the Covered Conduct.
- H. In separate actions brought by California and Florida, California and Florida also contend that Schering/Warrick submitted, or caused to be submitted, for payment by the Medicaid Program false, fraudulent, and excessive claims for reimbursement as a result of the Covered Conduct resulting in damage to California and Florida. Schering/Warrick and California, and Schering/Warrick and Florida will execute separate settlement agreements in exchange for the payment specified in Paragraph III.1 below and in accordance with any terms and conditions specified in such separate settlement agreements.

- I. This Agreement is the result of a compromise of disputed issues of law and fact, and the execution and delivery of this Agreement shall not constitute or be construed as an admission of fault, liability, or wrongdoing by any of the Parties, nor does it constitute evidence of any liability or unlawful conduct on the part of the Parties, and the Relator, California, and Florida will not urge or seek to admit this Agreement as evidence of any fault or liability of the Parties in any investigation, administrative claim, action, suit, or proceeding, or federal or state court or arbitration proceeding.
- J. Schering/Warrick deny all of the claims and allegations brought on behalf of the United States and by California and Florida, deny any wrongdoing, and deny that they have any liability relating to the Covered Conduct.
- K. To avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these disputed claims, and as a result of a mutual desire to settle their disputes, the Parties have reached a full, fair, and final settlement as set forth in this Agreement. The parties agree that this Agreement is not punitive in purpose or effect.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations set forth below in this Settlement Agreement, and for good and valuable consideration the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. In full and final settlement of all claims that were brought or that could have been brought by the Relator on behalf of the United States, and all claims that were brought or that could have been brought by the States of California and Florida, Schering/Warrick shall pay the sum of Fifty-Five Million Dollars (\$55,000,000) (the "Settlement Amount"). This Settlement

Amount is intended to resolve, fully and finally, all of the claims that were brought or could have brought on behalf of the United States arising out of the Covered Conduct, and also all claims that were brought or that could have been brought by the States of California and Florida as set forth more fully in the separate settlement agreements by and between Schering/Warrick and California and Schering/Warrick and Florida.

- 2. The allocation of the Settlement Amount among the United States, California, and Florida, and the Relator and their counsel is a matter that shall be handled separately by and among the United States, the Relator, the Relator's attorneys, California, and Florida without any involvement by Schering/Warrick. Each of the Parties agrees that Schering/Warrick was not consulted about the allocation, nor has Schering/Warrick had any input into the allocation. Each of California, Florida, the Relator on behalf of the United States, and the Relator's attorneys (i) shall agree to the allocation of the Settlement Amount among those Parties and (ii) also shall refrain from objecting to any of the settlements contemplated by this Settlement Agreement, or any terms thereof, including the allocation of the Settlement Amount and the payment of any Relator's Share, expenses, attorneys' fees, or costs related to the Civil Actions or the actions brought by California and Florida against Schering/Warrick.
- 3. It is the intention of all Parties to this Settlement Agreement that all amounts payable to the Relator and its attorneys be paid out of the Settlement Amount. To that end, the Parties agree as follows:
- (a) Each of the Parties to this Settlement Agreement agrees and acknowledges that the Relator is entitled under 31 U.S.C. § 3730(d), to a statutory percentage of the Settlement Amount allocated to the United States (the "Relator Share"). Determination of the Relator's

Share shall be handled separately between the United States, the Relator, and their attorneys and shall be paid by the United States to the Relator.

- (b) Each of the Parties to this Settlement Agreement further acknowledges and agrees that the Relator is entitled to receive reasonable expenses necessarily incurred in the prosecution of the Civil Actions (as the term is defined above), plus reasonable attorneys' fees and costs incurred in connection with those actions under 31 U.S.C. § 3730(d). Again, the Parties agree that these amounts shall be paid out of the Settlement Amount allocated to the United States. Accordingly, the Order of Dismissal with Prejudice that shall be presented to the Court jointly by the Relator and Schering/Warrick shall set forth the total amount of reasonable expenses and attorneys' fees being requested pursuant to 31 U.S.C. § 3730(d), in each Civil Action, which amounts shall be subtracted from the allocation determined payable to the United States.
- (c) Each of the Parties to this Settlement Agreement further acknowledges and agrees that the Relator and its attorneys may be entitled to Relator' shares, expenses, attorneys' fees, and costs under state law for efforts expended in connection with the actions brought against Schering/Warrick by the States of California and Florida. These amounts shall be paid out of those portions of the Settlement Amount allocated to California and Florida in accordance with the terms and conditions of the separate settlement agreements entered into by and between Schering/Warrick and California, and Schering/Warrick and Florida.
- (d) The Relator, California, and Florida, jointly and severally, agree to indemnify and hold Schering/Warrick harmless from and against any claim by any person or entity for expenses, attorneys' fees, and costs, and/or any portion of the Settlement Amount,

including a portion of the Relator' Share, that the person or entity is claiming is due, arising out of the Civil Actions.

4. Within fifteen (15) business days from the Effective Date of this Agreement, Schering/Warrick shall pay the Settlement Amount by wire transfer into an escrow account at Frontier Bank ("Escrow Agent") in accordance with the terms of the separate Escrow Agreement. The Escrow Agent shall hold the Settlement Amount and any interest earned thereon in escrow pursuant to the terms of the separate Escrow Agreement executed by an among the parties to this Settlement Agreement. The Escrow Agent shall not distribute any portion of the Settlement Amount until courts of competent jurisdiction have allowed and ordered (i) the dismissal with prejudice of the Civil Actions as contemplated by Paragraph III.7 below and (ii) the dismissal with prejudice of the actions brought by California and Florida against Schering/Warrick, and such orders have become final. Then, upon receiving written notice from the Relator's attorneys demonstrating to the reasonable satisfaction of the Escrow Agent that each of these four cases has been dismissed with prejudice, within three business days, the Escrow Agent shall distribute the Settlement Amount and any interest earned thereon, pursuant to written wire instructions and written instructions concerning the allocation of the Settlement Amount and any interest earned thereon received from the Relator's attorneys. Such written instructions concerning the allocation of the Settlement Amount and any interest earned thereon shall be agreed to, approved, and signed to indicate agreement to and approval of the allocation by the California Attorney General's Office on behalf of California, the Florida Attorney General's Office on behalf of Florida, the Relator, and the Relator's attorneys.

- 5. In consideration of the obligations of Schering/Warrick in this Settlement Agreement, and conditioned on Schering/Warrick's payment in full of the Settlement Amount in accordance with Paragraphs III.1 and III.4 above, the Relator on behalf of the United States and on behalf of the Relator, its predecessors, successors, subsidiaries, parents, assigns, and affiliates and any current or former shareholders, directors, officers, agents, employees, servants, and attorneys, fully and finally release, acquit, and forever discharge Schering/Warrick, their present and former parents, affiliates, divisions, and subsidiaries, their predecessors and successors, their current and former officers, directors, employees, agents, servants, and attorneys from any claim, action, suit, or proceeding, whether sealed or unsealed, whether civil or administrative (including for expenses, attorney fees, costs, penalties, punitive damages, liabilities, obligations, and expenses of every kind and however denominated) that the Relator has asserted or could have asserted on behalf of the United States or on its own behalf arising out of or related to the Covered Conduct for the Covered Drugs (as defined in Paragraph III.6 below) during the Relevant Period, including but not limited to the federal-share of any claim brought by a state arising out of or related to the Covered Conduct or Covered Drugs. This release further discharges Schering/Warrick from, among other things, any such civil obligation to the Relator or its attorneys, including any Relator's Share, expenses, attorneys' fees, and costs associated with the Civil Actions to which Relator or its attorneys may be entitled, except as provided for in this Settlement Agreement.
- 6. This Settlement is conditioned on the resolution by the Court of any potential issues concerning the compliance by Schering with the liability standards set forth in the Court's June 21, 2007 decision in MDL No. 1456. Since the inception of this litigation, it has been the Relator's position that AWPs for brand-name drugs that are set based on an industry standard

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20%-25% mark-up from a WAC at or about which substantial sales are made cannot form the basis for a false statement or False Claims Act violation. Consistent with this perspective, the Relator and Schering have reviewed the analyses of spreads (measured as the difference between AWP and AMP) and sales within 5% of WAC for the Schering brand drugs attached hereto as Exhibit A (the "Schering Covered Drugs")(the Warrick Covered Drugs and the Schering Covered Drugs together shall be known as the "Covered Drugs") (which analyses Schering provided to the United States Department of Justice in February 2008) and concluded that the patterns of spreads and sales at list price for those drugs fall within the parameters described above for which the MDL Court found no liability for the Schering-Plough brand drugs at issue in the MDL. The Relator made this determination on the basis of its independent pricing information and otherwise assumed that the confidential AMP information provided by Schering was the AMP data that Schering reported to CMS. To the extent that the United States Department of Justice has not reviewed and agreed to be bound by the analyses of spreads and sales at list price on the Schering brand drugs, the Relator and Schering have agreed that this Settlement is conditioned on an independent review by the Court of the analyses reflected in Exhibit A, and on the entry of findings of fact and rulings of law concerning the relevant drugs consistent with the agreement of the parties. More specifically, the parties have agreed, and seek the Court's independent concurrence, that neither the WACs nor the AWPs for the drugs shown in Exhibit A constitute false statements within the meaning of the False Claims Act and that claims for reimbursement based on such WACs and AWPs are neither deceptive nor unfair. These findings and rulings are necessary to assure that this Settlement resolves all claims of the United States to recover for any alleged injury to the Medicaid program as a result of the use of published prices for reimbursement of the Schering brand drugs shown in Exhibit A.

Accordingly, in order to effectuate this Settlement, the parties will jointly request the Court to schedule a prompt hearing to review the analysis of spreads, with notice and invitation to the Department of Justice to attend and participate in the hearing.

- Agreement, the Relator agrees that, upon execution of this Agreement by all Parties, they shall amend the complaint in the Florida Civil Action to assert claims under the federal False Claims Act as to all of the Covered Drugs to the fullest extent that such claims are cognizable and permissibly may be asserted against Schering/Warrick. Such amended complaint shall be in the form attached to this Settlement Agreement as Exhibit B. In further consideration of the obligations of Schering/Warrick in this Settlement Agreement, and conditioned upon Schering/Warrick's payment in full of the Settlement Amount in accordance with Paragraphs III.1 and III.4 above, the Relator and Schering/Warrick agree to jointly move for the entry of an order approving the settlement and dismissing the Florida and Massachusetts Civil Actions with prejudice in the form attached hereto as Exhibit C as soon as Schering/Warrick has satisfied its payment obligations under Paragraphs III.1 and III.4 above.
- 8. In consideration of the obligations of the Relator set forth in this Settlement Agreement, Schering/Warrick, on behalf of themselves and their predecessors, successors, subsidiaries, parents, assigns, and affiliates and any current or former shareholders, directors, officers, agents, employees, servants, and attorneys fully and finally release the Relator, its present and former parents, affiliates, divisions, and subsidiaries, their predecessors and successors, its current and former officers, directors, employees, agents, servants, and attorneys from any claims relating to the Covered Conduct, or the investigation or litigation of claims

relating to the Covered Conduct for the Relevant Period which Schering/Warrick have or could have asserted.

- 9. Notwithstanding any other term of this Settlement Agreement, including the release provisions in Paragraphs III.5 and III.8 above, specifically reserved and excluded from the scope and terms of this Settlement Agreement, and from the scope and terms of the releases, as to any entity or person (including the Parties), are any and all of the following:
 - (a) Any claims based upon such obligations as are created by this Settlement Agreement;
 - (b) The subrogation rights to claims for personal injury or injury to real or personal property arising from usage by a participant in the Medicaid Program of any of the Subject Drugs covered there under;
 - (c) Any claims based on a failure to deliver products or services due;
 - (d) Any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
 - (e) Any criminal liability not specifically released by this Settlement Agreement; and
 - (f) Any express or implied warranty claims or other claims for defective or deficient products and services provided by Defendants.
- 10. The Parties each represent that this Settlement Agreement is freely and voluntarily entered into without any degree of duress whatsoever.
- 11. Except as expressly provided to the contrary in this Settlement Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Settlement Agreement.
- 12. This Settlement Agreement shall be governed by the laws of the United States.

 The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement shall be the United States District Court for the District of Massachusetts and that the United States District Court for the District of Massachusetts shall

retain continuing jurisdiction over the enforcement of this Settlement Agreement and all releases provided for herein, including for purposes of issuing an injunction in protection of the Court's jurisdiction to enforce the terms, conditions, and releases provided for in this Settlement Agreement.

- 13. This Settlement Agreement, together with the separate settlement agreements entered into between Schering/Warrick and California and Schering/Warrick and Florida and the Escrow Agreement, shall constitute the complete agreement between the Parties with regard to the Covered Conduct. This Settlement Agreement may not be amended except by written consent of all of the Parties.
- 14. The individuals signing this Agreement on behalf of Schering/Warrick represent and warrant that they are authorized by Schering-Plough, Schering, and Warrick to execute this Settlement Agreement. The individuals signing on behalf of the Relators and their attorneys represent and warrant that they are authorized by that Relator to execute this Settlement Agreement. The California and Florida signatories represent that they are signing this Settlement Agreement in their official capacities and that they are authorized to execute this Settlement Agreement.
- 15. This Settlement Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.
- 16. This Settlement Agreement is binding on Schering, Schering-Plough, and Warrick's successors, transferees, heirs, and assigns.
- 17. This Settlement Agreement is binding on Relator's successors, transferees, heirs, and assigns.

- 18. This Settlement Agreement has been negotiated at arm's length and between and among persons sophisticated and knowledgeable in the matters dealt with in this Settlement Agreement. In addition, this Settlement Agreement was drafted by experienced and knowledgeable legal counsel for each of the Parties. Accordingly, none of the Parties shall be entitled to have any provisions of the Settlement Agreement construed against any of the other Parties in accordance with any rule of law, legal decision, or doctrine regarding the construction of ambiguous language in a contract. The provisions of this Settlement Agreement shall be interpreted in a reasonable manner to effect the purposes of the Parties and this Settlement Agreement.
- 19. If any provision of this Settlement Agreement, or the application thereof, shall for any reason or to any extent be construed by a court of competent jurisdiction to be invalid or unenforceable, the remainder of this Settlement Agreement, and application of such provision to other circumstances, shall remain in effect and be interpreted so as best reasonably to effect the intent of the Parties. Notwithstanding the foregoing, if either the payment or any of the release provisions hereof are found to be unenforceable or invalid by a court of competent jurisdiction, then such invalidity or unenforceability shall be cause for voiding the entire Settlement Agreement at the election of the Party the interests of which are injured by the finding of invalidity or unenforceability.
- 20. This Settlement Agreement is effective on the date of signature of the last signatory to this Settlement Agreement ("Effective Date"). Facsimiles or .pdfs of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

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SCHERING-PLOUGH, SCHERING, AND WARRICK

Defendant Warrick Pharmaceuticals Corporation

BY

Elpidio Villarreal

Vice President & Associate General Counsel

Defendant Schering Corporation

BY

Elpidio Villarreal

Vice President & Associate General Counsel

Defendant Schering-Plough Corporation

BY

Thomas Sabatino

Executive Vice President & General Counsel

RELATOR AND IT'S ATTORNEY

By: James J. Breen The Breen law Firm, P.A. P.O. Box 297470 Pembroke Pines, FL 33029 Counsel to Ven-A-Care of the Fl		15/09	
	,		
By: T. Mark Jones, President Ven-A-Care of the Florida Keys,	Dated:		
	CALIFORNIA		
State of California Office of the Attorney General			
By:			
Date:	1		
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Nicholas Paul Supervising Deputy Attorney General Bureau of Medi-Cal Fraud & Elder Abus Office of the Attorney General 1455 Frazee Road, Suite 315 San Diego, CA 92108	se		
	FLORIDA		
State of Florida Office of the Attorney General			
Ву:			
Date:	 -		

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RELATOR AND IT'S ATTORNEY

D.		Dated:
By:	James J. Breen	Dated.
	The Breen law Firm, P.A.	
	P.O. Box 297470	
	Pembroke Pines, FL 33029	
	Counsel to Ven-A-Care of the	Florida Keys, Inc
Ву	T. Mark Jones, President Ven-A-Gare of the Florida Ke	Dated: 6/25/0°
	/	CALIFORNIA
	e of California ce of the Attorney General	
Ву:		
Date	·	
Supe Bure Offi 1455	nolas Paul ervising Deputy Attorney General eau of Medi-Cal Fraud & Elder A ce of the Attorney General 5 Frazee Road, Suite 315 Diego, CA 92108	
		FLORIDA
Stat	te of Florida	
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OIL	ice of the Attorney General	
By:		
Date	e:	

Exhibit A

Analysis of Schering's Brand Drugs

February 4, 2008



Boston New York Palo Alto San Francisco Washington, DC

Overview of Analysis



Analysis Done:

- Applying Judge Saris' Criteria for Determining Liability
- On a Drug-By-Drug Basis for Each of Schering's Prescription Drugs for Years During Which They Were Actively Marketed
 - We did not perform an analysis for periods when a drug had been listed as "obsolete" (FDB) or "inactive" (Medispan), had been publicly announced as being moved to over-the-counter, had become "functionally obsolete" (i.e., gross sales to the AMP classes of trade dropped to less than 10% of sales in prior quarters and AMP units were generally negative), or for which there were not at least six months of sales data for sales made to the AMP classes of trade
- Includes an Analysis of All Drugs at Issue in Any State Case in Which Schering or Schering-Plough Had Been Sued as of September 21, 2007
- Analysis Completed for Likely Statute of Limitations Period

Judge Saris' Criteria For Determining Liability



Applying Judge Saris' criteria, there is no liability for any Schering-brand drug at issue in any of the state cases.

Judge Saris' Criteria

- "First, the most important inquiry asks: were there egregious spreads above the 30% yardstick expected in the industry? In particular, I focus on the extent and duration of the spreads to evaluate egregiousness." In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20, 101-02 (D. Mass. 2007).
 - An "isolated, anomalous occurrence" of a spread, even one of a "significant magnitude," does not give rise to liability in Judge Saris' view. *Id.* at 108.

Judge Saris' Criteria For Determining Liability (cont.)



- "Also relevant to this analysis is the legitimacy of the list price from which the markup is derived: Is it a real list price at which substantial sales were made or an unfair and deceptive price used to jack up the AWP?" *Id.* at 102.
 - "I find and hold that if more than 50 percent of all sales were made at or about the list price, the list price will not be deemed fictitious." *Id.* at 105.
 - "[A]t or about the list price" is defined as "within 5% of the list price [WAC]." In re Pharm. Indus. Average Wholesale Price Litig., MDL No. 1456, 01-CV-12257-PBS, at *6 (D. Mass Nov. 1, 2007)
- "Third, did the defendant engage in a proactive scheme to market the spread" 491 F. Supp. 2d 20 at 102.

The Schering-Brand Drugs



- As to the particular drugs at issue in the MDL, Judge Saris concluded as follows:
 - Temodar: "[A]II spreads are below 30%"; "I therefore find no liability." *Id.* at 108.
 - Intron A: As to the physician-administered NDCs, "the spread exceeds 30% in only 3 years, 1996, 2001 and 2002. The highest spread is 32.6% in 2001." "Given the isolated, minor spreads and little evidence of spread marketing, I find no liability for...Intron-A." Id.

The Schering-Brand Drugs (cont.)



- Proventil: "Although there are spreads consistently in the 30%-60% range for 1992-1997, from 1998 until 2003 there is only a single occurrence of a spread exceeding 30%. In 2002, one of the four Proventil NDCs had a spread of 163%." *Id.* at 108. "Although the spread in 2002 is of significant magnitude, it is an isolated, anomalous occurrence on one of the four Proventil NDCs. As such, I do not find [liability]." *Id.* at 108.
- In addition, Judge Saris found "no evidence" of Schering's "marketing the spread." See In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d at 108.

CMS Data Error



- There is an apparent error with the CMS reimbursement data for Q3 2003. It appears that Tennessee submitted grossly overstated reimbursement numbers to CMS for that quarter for many drugs.
- Below is an example of the CMS reimbursement amounts for Elocon to illustrate the error:

			Reimbursen	nent Amount	
Drug Name	NDC	Q1	Q2	Q3	Q4
			(Dol	lars)	
Tennessee					
Elocon	00085085401	\$630	\$783	\$7,500,000	\$2,451
Elocon	00085085402	\$1,508	\$1,577	\$13,300,000	\$6,465
All Other States					
Elocon	00085085401	\$38,213	\$71,955	\$82,690	\$82,852
Elocon	00085085402	\$204,876	\$252,594	\$245,743	\$235,316
		Tennessee Sha	re of National	Reimbursement /	Amount
			(Per	cent)	
Elocon	00085085401	1.6%	1.1%	98.9%	2.9%
Elocon	00085085402	0.7%	0.6%	98.2%	2.7%

- This Q3 2003 increase in reimbursement is not reflected in Schering's sales data.
- This error does not affect the analysis of Schering's spread or sales at WAC.
- As a result of this error, the 2003 CMS reimbursement data is unreliable.

Cedax



☑ No Liability Applying Judge Saris' Criteria

		1997			1998			1999	1		2000			2001			2002			2003	
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List		Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb
000850691 ¹	23%	100%	\$3,555,222	23%	97%	\$3,009,547	23%	92%	\$1,791,191	56%	99%	\$947,105									
0008507772	25%	100%	\$6,652,342	26%	99%	\$5,549,400	25%	97%	\$3,688,361	60%	100%	\$2,254,018									
000850834 ³	26%	99%	\$6,862	27%	87%	\$16,397	27%	95%	\$29,242												

- Only "isolated" occurrences of spreads above 30% and only at the end of the drug's life
- Always "substantial sales" at WAC
- Cedax became obsolete in 2000/2001

			FDB	Medispan		within NDC9 solete/Inactive	Date of	Date
Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Inactive Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000850691	01/08/96	05/31/01	04/16/01	07/02/01	07/02/01	01/18/00	02/17/00
2	000850777	01/08/96	03/28/01	03/28/01	07/02/01	07/02/01	01/17/00	02/22/00
3	000850834	01/27/97	09/01/00	09/01/00	09/01/00	09/01/00	01/14/00	01/19/00

Celestone Soluspan



☑ No Liability Applying Judge Saris' Criteria

		1997			1998			1999			2000			2001			2002			2003†	
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb												
000850011 ¹	22%	98%	\$77,809	23%	99%	\$74,646	20%	97%	\$75,614	11%	98%	\$64,397	23%	99%	\$32,337						
000850566 ²	25%	15%	\$1,951,038	26%	14%	\$2,208,085	25%	21%	\$3,632,602	30%	10%	\$4,199,478	24%	31%	\$2,742,699	25%	29%	\$903,054	31%	20%	\$83,354
0008509423	23%	89%	\$67,908	23%	97%	\$16,126	22%	96%	\$15,822	21%	96%	\$16,769	26%	95%	\$14,637	25%	96%	\$14,200	29%	85%	\$13,449

† On February 27, 2003, FDB increased its mark-up of AWP from 20% to 25%

- Only a single occurrence of a spread above 30%
 - Occurs after First DataBank increased its mark-up of AWP from 20% to 25%, an occurrence over which Schering had no control
- NDC 00085-0566 is a syringe sold mostly to customers outside the AMP classes of trade such as hospitals
- NDC 0085-0111 became obsolete in 2002

			FDB	Medispan	If All NDCs v Become Obs		Date of	Date
Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Inactive Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000850011	01/01/82	05/17/02	05/17/02	05/17/02	05/17/02	10/22/01	11/27/01
2	000850566	01/01/82					09/28/07	09/30/07
3	000850942	01/01/82					09/26/07	09/26/07

Clarinex



☑ No Liability Applying Judge Saris' Criteria

		1997			1998			1999			2000			2001			2002	t		2003	3*
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb															
000851264 ¹																24%	96%	\$49,704,091	28%	95%	\$260,275,546
000851280 ²																			31%	87%	\$32,098,566
000851334 ³																					

† On October 3, 2002, FDB increased its mark-up of AWP from 20% to 25%

- Only a single occurrence of a spread above 30%
- Always "substantial sales" at WAC
- First Clarinex NDC was launched in 2002

			FDB	Medispan	If All NDCs v Become Obs		Date of	Date
Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Inactive Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000851264	12/26/01					09/30/07	09/30/07
2	000851280	05/21/03	08/29/05	08/29/05	08/29/05	08/29/05	08/02/07	08/02/07
3	000851334	12/22/04					09/26/07	09/26/07

^{*} CMS reimbursement data for Q3 2003 for NDC 00085-1264 appear to be inaccurate, resulting in an inflated Medicaid reimbursement amount for 2003

Claritin



☑ No Liability Applying Judge Saris' Criteria

		199	7		199	3		1999	9		200	0		200	1		2002	2†		2003	
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb									
000850458 ¹	23%	95%	\$60,882,964	23%	95%	\$77,248,678	23%	95%	\$99,039,511	24%	93%	\$118,712,743	25%	91%	\$156,252,015	33%	21%	\$154,323,713			
0008506122	23%	97%	\$6,843,637	23%	96%	\$9,249,583															
000851128 ³	23%	99%	\$2,816,313	23%	97%	\$11,416,328	23%	94%	\$37,817,163	23%	92%	\$51,853,573	25%	93%	\$70,998,485	32%	45%	\$82,061,460			
0008512234							23%	97%	\$2,417,920	23%	95%	\$10,043,475	25%	96%	\$16,769,444	32%	30%	\$19,958,445			

† On March 1, 2002, FDB increased its mark-up of AWP from 20% to 25%

- Only "isolated" occurrences of spreads above 30%
 - All occur after First DataBank increased its mark-up of AWP from 20% to 25%, an occurrence over which Schering had no control
- "Substantial sales" at WAC for all years until 2002, when Claritin was announced to be going over-thecounter
- There are only three periods during which the spread was above 30% for which sales at WAC were below 50% and all occur after First DataBank increased its mark-up and at the end of the drug's life

			FDB Obsolete	Medispan Inactive	If All NDCs v Become Obse		Date of	Date of Last
Foot- note	NDC-9	Date Added	Date of First NDC	Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Sales to AMP Classes of Trade	Gross Sales Activity
1	000850458	04/14/93	04/01/01	04/01/01	03/01/04	01/27/03	12/20/06	04/03/07
2	000850612	10/15/96	05/21/99	05/21/99	05/21/99	05/21/99	04/23/01	04/23/01
3	000851128	02/06/97	05/01/04	01/27/03	05/01/04	01/27/03	01/29/07	01/29/07
4	000851223	05/25/99	01/27/03	01/27/03	01/27/03	01/27/03	12/20/06	04/03/07

- Schering announced that Claritin would be going overthe-counter in March 2002 and it was approved for over-the-counter sales in November 2002
- NDC 00085-0612 became obsolete in 1999

Claritin-D



☑ No Liability Applying Judge Saris' Criteria

		1997	7		199	3		199	9		200)		200	1		2002	t		2003	
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List		Spread	Sales at List	Reimb	Spread	Sales at List	Reimb									
000850635 ¹	23%	98%	\$17,264,263	23%	96%	\$18,699,510	23%	98%	\$20,580,052	23%	96%	\$22,390,041	25%	66%	\$28,546,388	32%	39%	\$23,172,741			
000850640 ²	23%	98%	\$2,888,049																		
0008512333							23%	97%	\$14,193,156	23%	97%	\$23,678,567	25%	66%	\$33,594,846	\$32%	21%	\$36,520,912			

† On March 1, 2002, FDB increased its mark-up of AWP from 20% to 25%

- Only "isolated" occurrences of spreads above 30%
 - All occur after First DataBank increased its mark-up of AWP from 20% to 25%, an occurrence over which Schering had no control
- "Substantial sales" at WAC for all years until 2002, when Claritin-D was announced to be going over-thecounter
- There are only two periods during which the spread was above 30% for which sales at WAC were below 50% and all occur after First DataBank increased its mark-up and at the end of the drug's life

			FDB	Medispan	If All NDCs v Become Obs		Date of	Date
Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Inactive Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000850635	11/15/94	01/27/03	01/27/03	12/01/03	01/27/03	08/07/07	08/07/07
2	000850640	08/27/96	12/07/98	12/07/98	12/07/98	12/07/98	09/20/99	09/24/99
3	000851233	12/07/98	08/01/03	01/27/03	08/01/03	01/27/03	10/16/03	01/31/04

- Schering announced that Claritin-D would be going over-the-counter in March 2002 and it was approved for over-the-counter sales in November 2002
- NDC 00085-0640 became obsolete in 1998

Diprolene



☑ No Liability Applying Judge Saris' Criteria

		1997	•		1998			1999	ı		2000			2001			2002	t		2003	3*
NDC-9	Spread	Sales at List	Reimb																		
0008505171	27%	92%	\$1,901,470	26%	94%	\$1,674,339	27%	93%	\$3,276,520	27%	93%	\$4,943,686	28%	92%	\$6,207,621	29%	76%	\$4,231,998	32%	82%	\$70,079,310
000850575 ²	26%	89%	\$654,642	25%	91%	\$434,370	24%	90%	\$563,497	26%	93%	\$684,996	27%	93%	\$605,280	28%	77%	\$417,203	35%	54%	\$2,078,847
000850634 ³	27%	94%	\$507,496	28%	95%	\$515,993	28%	95%	\$616,592	29%	94%	\$689,906	30%	94%	\$790,975	32%	43%	\$443,014	33%	68%	\$8,105,544
0008509624	23%	94%	\$629,335	23%	94%	\$628,777	23%	94%	\$696,549	24%	93%	\$769,328	24%	94%	\$918,690	24%	87%	\$1,007,648	29%	88%	\$13,417,944

† On December 10, 2002, FDB increased its mark-up of AWP from 20% to 25%

- Only "isolated" occurrences of spreads above 30%
 - All but one occur after First DataBank increased its mark-up of AWP from 20% to 25%, an occurrence over which Schering had no control
- "Substantial sales" at WAC for all NDCs in all years except for a single NDC (00085-0634) in 2002

			FDB	Medispan		within NDC9 solete/Inactive	Date of	Date
Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Inactive Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000850517	03/19/87	06/04/96	04/01/96			09/25/07	09/27/07
2	000850575	08/07/83	06/04/96	04/01/96			09/25/07	09/27/07
3	000850634	12/05/91	06/04/96	04/01/96	08/31/04	02/24/06	12/20/06	12/20/06
4	000850962	05/19/88					09/26/07	09/27/07

 There is only one period during which the spread was above 30% for which sales at WAC were below 50%

^{*} CMS reimbursement data for Q3 2003 for Diprolene appear to be inaccurate, resulting in an inflated Medicaid reimbursement amount for 2003

Diprosone



☑ No Liability Applying Judge Saris' Criteria

		1997			1998			1999			2000			2001			2002			2003	
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb												
000850475 ¹	21%	79%	\$22,397	22%	80%	\$18,034															
000850853 ²	28%	87%	\$34,879	35%	82%	\$26,669	32%	80%	\$26,048	33%	95%	\$20,052	6%	96%	\$16,263						

- Always "substantial sales" at WAC
- There is no period during which the spread was above 30% for which sales at WAC were below 50%
- NDC 00085-0475 became obsolete in 1999
- The last gross sale to the AMP classes of trade for NDC 00085-0853 occurred in Q4 2001

			FDB	Medispan	If All NDCs v Become Obse		Date of	Date
Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Inactive Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000850475	01/01/82	07/22/99	09/17/03	07/22/99	09/17/03	03/03/00	04/12/00
2	000850853	01/01/82		09/17/03		09/17/03	11/18/01	12/06/01

Elocon



☑ No Liability Applying Judge Saris' Criteria

		1997	7		1998	В		1999)		200)		2001	1		2002	t		200	3*
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb												
000850370 ¹	29%	94%	\$3,231,560	29%	95%	\$3,068,386	29%	95%	\$2,506,020	30%	95%	\$2,733,119	32%	95%	\$3,658,106	30%	81%	\$2,402,881	42%	39%	\$7,820,431
0008505672	30%	94%	\$14,794,362	29%	96%	\$13,607,984	30%	96%	\$10,993,056	30%	96%	\$11,929,425	31%	95%	\$14,332,679	32%	70%	\$8,099,916	36%	78%	\$167,261,249
000850854 ³	23%	96%	\$1,417,722	23%	97%	\$1,316,406	23%	97%	\$1,013,743	23%	96%	\$1,027,877	24%	97%	\$1,414,811	24%	98%	\$2,150,800	32%	46%	\$22,027,652

† On December 10, 2002, FDB increased its mark-up of AWP from 20% to 25%

- Only a handful of spreads above 30%
- "Substantial sales" at WAC for the entire period for the NDC with the greatest Medicaid reimbursement (00085-0567), and "substantial sales" at WAC for the other NDCs in every year except 2003
- If All NDCs within NDC9 FDB Medispan Recome Obsolete/Inactive Date of Date Obsolete Last Gross of Last Inactive Obsolete Date Inactive Date Sales to AMP Date of Date of Gross Sales First NDC First NDC of Last NDC Classes of Trade Activity 000850370 07/02/87 09/26/07 09/26/07 000850567 07/02/87 09/26/07 09/30/07 000850854 05/04/89 09/26/07 09/26/07
- There are only two periods during which the spreads were above 30% for which sales at WAC were below 50%
 - All occur after First DataBank increased its mark-up of AWP from 20% to 25%, an occurrence over which Schering had no control

^{*} CMS reimbursement data for Q3 2003 for Elocon appear to be inaccurate, resulting in an inflated Medicaid reimbursement amount for 2003

Eulexin



☑ No Liability Applying Judge Saris' Criteria

		1997	•		1998	1		1999)		2000	ı		2001			2002			2003	
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb															
000850525 ¹	23%	69%	\$6,272,686	23%	70%	\$5,584,801	23%	67%	\$5,223,175	24%	64%	\$5,324,247	25%	49%	\$4,874,861			\$1,632,052			\$614,925

- No spreads above 30%
- "Substantial sales" at WAC in all but one year
- Eulexin became functionally obsolete in Q2 2002

			FDB	Medispan	If All NDCs v Become Obse		Date of	Date
Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Inactive Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000850525	02/09/89	10/01/93	09/30/93		04/10/05	03/28/05	04/03/07

Foradil



Mo Liability Applying Judge Saris' Criteria

		1997			1998			1999			2000			2001			2002			2003	t
NDC-9	Spread	Sales at List	Reimb																		
000851401 ¹																			29%	75%	\$20.075,841
0008514022																					

† On July 1, 2003, FDB increased its mark-up of AWP from 20% to 25%

- No spreads above 30%
- "Substantial sales" at WAC
- NDC 00085-1401 was not launched until Q2 2003
- NDC 00085-1402 was not launched until Q3 2003 and no analysis was done on the part year

Ī				FDB	Medispan		within NDC9 colete/Inactive	Date of	Date
	Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Inactive Date of First NDC	of Obsolete Date Inactive Date		Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
Ι	1	000851401	06/25/03					09/29/07	09/29/07
	2	000851402	07/16/03					09/26/07	09/30/07

Fulvicin



☑ No Liability Applying Judge Saris' Criteria

		1997			1998			1999			2000			2001			2002			2003	
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb
000850496 ¹	25%	88%	\$149,098	23%	89%	\$98,296	23%	87%	\$84,451	23%	81%	\$89,695	25%	74%	\$121,643						

- No spreads above 30%
- Always "substantial sales" at WAC
- Fulvicin became obsolete in 2002

			FDB Obsolete	Medispan Inactive	If All NDCs v Become Obse		Date of Last Gross	Date of Last
Foot- note	NDC-9	Date Added	Date of First NDC	Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Sales to AMP Classes of Trade	Gross Sales Activity
1	000850496	01/01/82	05/17/02	05/17/02	05/17/02	05/17/02	10/02/02	10/24/02

IMDUR



		199	7		1998	3		199	9		2000			2001			2002	t		2003	į
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb
000851153 ¹	23%	97%	\$2,627,624	23%	97%	\$4,260,821	24%	94%	\$5,663,336	30%	66%	\$4,152,632	37%	78%	\$1,766,057	29%	83%	\$1,079,811	34%	83%	\$1,452,451
000853306 ²	23%	94%	\$8,429,229	23%	95%	\$16,994,784	26%	92%	\$11,238,458	37%	66%	\$3,062,093	50%	79%	\$1,518,837	29%	85%	\$961,761	29%	87%	\$399,463
000854110 ³	23%	91%	\$26,317,644	23%	94%	\$34,332,321	27%	88%	\$14,584,601	37%	64%	\$4,452,270	54%	70%	\$2,274,036	30%	80%	\$1,144,343	29%	88%	\$437,772

† On March 1, 2002, FDB increased its mark-up of AWP from 20% to 25%

- Only a handful of spreads above 30%
- Always "substantial sales" at WAC

			FDB Obsolete	Medispan Inactive	If All NDCs v Become Obso		Date of	Date
Foot- note	NDC-9	Date Added	Date of First NDC	Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000851153	05/05/95	01/16/06	01/16/06	01/16/06	01/16/06	11/07/06	11/07/06
2	000853306	12/26/95	01/16/06	09/27/05	01/16/06	09/27/05	12/20/06	12/20/06
3	000854110	08/30/93	01/16/06	01/16/06	01/16/06	01/16/06	12/20/06	12/20/06

Intron A



☑ No Liability Applying Judge Saris' Criteria

		1997			1998			1999			2000			2001			2002	t		2003*	,
NDC-9	Spread	Sales at List	Reimb																		
000850120 ¹	23%	80%	\$7,038,008	23%	73%	\$855,741	23%	64%	\$451,047	25%	39%	\$372,203	24%	41%	\$213,052						
000850285 ²	23%	49%	\$696,665	23%	64%	\$417,311	23%	57%	\$263,068	25%	49%	\$250,197	23%	55%	\$151,858						
000850539 ³	23%	69%	\$856,040	22%	69%	\$845,922	23%	62%	\$617,269	25%	64%	\$702,585	24%	64%	\$688,166	26%	76%	\$552,928	28%	73%	\$955,652
0008505714	28%	60%	\$1,211,940	24%	58%	\$685,691	23%	50%	\$323,144	25%	35%	\$274,682	24%	38%	\$440,580	26%	59%	\$322,309	28%	55%	\$675,567
0008506475	25%	79%	\$5,557,426	23%	79%	\$3,331,248	23%	80%	\$1,663,590	25%	54%	\$664,473	23%	62%	\$632,297						
0008506896																					
000850769 ⁷																					
0008509238																					
000850953 ⁹																					
000851110 ¹⁰	23%	74%	\$702,591	23%	77%	\$710,746	23%	69%	\$517,591	25%	60%	\$338,680	24%	46%	\$242,129	26%	75%	\$301,973	29%	63%	\$758,591
00085113311	23%	71%	\$254,643	83%	77%	\$705,955	82%	76%	\$696,746	25%	60%	\$510,335	24%	54%	\$408,218	26%	72%	\$404,735	28%	64%	\$628,875
000851168 ¹²	23%	81%	\$292,444	23%	74%	\$531,874	23%	81%	\$661,294	25%	69%	\$694,594	25%	60%	\$613,785	26%	78%	\$388,485	29%	60%	\$909,655
00085117913	22%	78%	\$673,015	23%	77%	\$1,555,343	23%	71%	\$1,316,781	25%	55%	\$905,908	24%	56%	\$773,801	25%	80%	\$500,049	29%	63%	\$1,253,575
00085118414	23%	90%	\$4,661,355	23%	88%	\$7,143,615	23%	83%	\$3,677,589	25%	49%	\$1,651,253	24%	62%	\$1,021,972	23%	83%	\$656,401			
00085119115	23%	90%	\$1,368,235	23%	82%	\$2,494,808	23%	83%	\$1,556,326	25%	65%	\$925,085	23%	70%	\$690,608	23%	76%	\$420,089			
000851235 ¹⁶							23%	89%	\$383,392	25%	78%	\$732,585	24%	78%	\$812,195	25%	85%	\$750,732	29%	68%	\$1,600,773
00085124217							23%	89%	\$623,348	26%	77%	\$1,405,896	24%	80%	\$1,272,763	24%	84%	\$936,673	29%	80%	\$5,382,130
00085125418							23%	87%	\$378,879	25%	82%	\$653,856	25%	74%	\$1,036,564	25%	88%	\$1,138,907	29%	81%	\$3,018,152

† On September 11, 2002, FDB increased its mark-up of AWP from 20% to 25%

^{*} CMS reimbursement data for Q3 2003 at least for certain NDCs (00085-1235, 00085-1242, and 00085-1254) and perhaps others appear to be inaccurate, resulting in an inflated Medicaid reimbursement amount for 2003

Intron A (cont.)



- Judge Saris examined the physician-administered Intron A NDCs* in the MDL and found "no liability"
- The spread and sales at WAC analyses for the self-administered NDCs yield very similar results
- Spreads above 30% only for a single NDC (00085-1133) and only in two years
- "Substantial sales" at WAC for most years and NDCs
- There is no period during which the spread was above 30% for which sales at WAC were below 50%

^{*} Judge Saris examined the following Intron A NDCs: 00085-068901, 00085-111001, 00085-028502, 00085-057102, 00085-057106, and 00085-053901

Intron A (cont.)



			FDB	Medispan		within NDC9 colete/Inactive	Date of	Date
Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Inactive Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000850120	06/12/86	01/30/96	02/01/96	09/30/02	02/24/06	10/29/02	07/11/03
2	000850285	06/12/86	07/31/02	02/24/06	07/31/02	02/24/06	08/07/02	01/07/04
3	000850539	12/01/88					09/25/07	09/27/07
4	000850571	06/12/86	03/17/97	04/30/97			09/26/07	09/28/07
5	000850647	06/12/86	03/17/97	04/30/97	05/17/02	05/17/02	01/14/02	11/08/02
6	000850689	08/10/92	12/19/95	01/16/96	12/19/95	01/16/96	03/13/96	06/24/96
7	000850769	05/18/93	03/17/97	03/17/99	03/17/97	03/17/99	05/13/97	11/21/97
8	000850923	05/18/93	03/17/97	05/02/97	03/17/97	05/02/97	05/05/97	01/13/98
9	000850953	01/27/95	03/17/97	01/01/97	03/17/97	01/01/97	06/12/97	08/19/97
10	000851110	12/19/95					09/26/07	09/26/07
11	000851133	01/30/97					09/26/07	09/27/07
12	000851168	01/30/97					09/26/07	09/27/07
13	000851179	01/30/97	12/14/99	02/24/06			12/20/06	09/05/07
14	000851184	01/30/97	12/14/99	02/24/06	09/30/03	02/24/06	02/20/03	03/20/03
15	000851191	01/30/97	12/14/99	12/14/99	04/29/03	04/29/03	10/08/02	12/12/02
16	000851235	07/14/98					09/26/07	09/27/07
17	000851242	07/14/98					09/26/07	09/27/07
18	000851254	07/14/98					09/26/07	09/26/07

- The NDCs 00085-0120, 00085-0285, and 00085-0647 became obsolete in 2002
- Certain NDCs (00085-0689, 00085-0769, 00085-0923, and 00085-0953) became obsolete before or during 1997
- NDCs 00085-1184 and 00085-1191 became obsolete in 2003
- NDCs 00085-1235, 00085-1242, and 00085-1254 were launched in Q3 1998 and no analysis was done for that part year

K-Dur



		199	7		1998	3		1999)		2000)		2001	l		2002			2003	*†
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb												
000850263 ¹	23%	84%	\$2,884,490	23%	88%	\$3,493,138	23%	90%	\$3,952,743	24%	86%	\$4,207,433	25%	70%	\$4,172,036	25%	38%	\$580,840	24%	86%	\$11,713,792
0008507872	24%	89%	\$34,359,877	23%	91%	\$40,319,803	23%	90%	\$44,906,559	25%	85%	\$47,567,069	26%	73%	\$44,891,141	28%	34%	\$5,462,744	38%	73%	\$79,380,621

† On February 27, 2003 FDB increased its mark-up of AWP from 20% to 25%

- Only a single "isolated" occurrence of a spread above 30%
- "Substantial sales" at WAC for both NDCs in every year except 2002
- There is no period during which the spread was above 30% for which sales at WAC were below 50%

			FDB	Medispan		within NDC9 colete/Inactive	Date of	Date
Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Inactive Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000850263	01/22/87	06/23/04	12/31/06		12/31/06	08/02/07	09/05/07
2	000850787	01/22/87	06/23/04	10/20/06		12/31/06	06/12/07	09/05/07

^{*} CMS reimbursement data for Q3 2003 for K-Dur appears to be inaccurate, resulting in an inflated Medicaid reimbursement amount for 2003

Lotrimin



		1997	,		1998			1999			200	0		2001			2002			2003	
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb
000850182 ¹	27%	68%	\$523,414	26%	66%	\$337,193	23%	62%	\$204,551	24%	58%	\$133,792	27%	52%	\$108,469						
000850613 ²	24%	63%	\$1,459,754	24%	71%	\$734,721	31%	82%	\$464,197	29%	91%	\$348,588	20%	87%	\$260,149						
000850707 ³	23%	78%	\$394,939	23%	74%	\$340,912	23%	76%	\$288,866	24%	75%	\$258,636	25%	71%	\$385,399						

- Only a single "isolated" occurrence of a spread above 30%
- Always "substantial sales" at WAC
- There is no period during which the spread was above 30% for which sales at WAC were below 50%
- Lotrimin became obsolete in 2002

			FDB	Medispan		within NDC9 solete/Inactive	Date of	Date
Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Inactive Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000850182	01/01/82	05/17/02	05/17/02	05/17/02	05/17/02	08/14/03	08/14/03
2	000850613	01/01/82	08/11/97	08/11/97	05/17/02	05/17/02	10/09/03	10/09/03
3	000850707	04/29/84	05/17/02	05/17/02	05/17/02	05/17/02	02/03/04	02/03/04

Lotrisone



		199	7		199	8		199	9		200	0		200	1		2002	: †		200	3*
NDC-9	Spread	Sales at List	Reimb																		
000850809 ¹													34%	47%	\$14,112,441	45%	94%	\$11,162,827	28%	85%	\$104,169,698
0008509242	25%	90%	\$44,744,866	25%	90%	\$48,695,985	25%	88%	\$52,509,237	26%	86%	\$56,541,114									

† On March 1, 2002, FDB increased its mark-up of AWP from 20% to 25%

- NDC 00085-0809 was launched in 2001 when NDC 00085-0924 became obsolete
- For NDC 00085-0924, no spreads above 30% and always "substantial sales" at WAC
- For the entire period for both NDCs, there is only one instance in which the spread was above 30% for which sales at WAC were below 50%

			FDB	Medispan		within NDC9 solete/Inactive	Date of	Date
Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Inactive Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000850809	01/03/01					09/25/07	09/25/07
2	000850924	07/01/84	06/01/01		06/01/01		09/26/07	09/27/07

^{*} CMS reimbursement data for Q3 2003 for the NDC 00085-0809 appear to be inaccurate, resulting in an inflated Medicaid reimbursement amount for 2003

Nasonex



☑ No Liability Applying Judge Saris' Criteria

		1997			1998			199	9		2000)		2001	I		2002	t		200	3*
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	
000851197 ¹				25%	n/d ◊	\$3,896,561	23%	92%	\$21,020,482	24%	88%	\$36,112,036	25%	92%	\$55,970,117	30%	91%	\$66,047,098	28%	94%	\$138,787,416
000851288 ²																					

♦ FDB has no listed WAC during 1998

† On March 1, 2002, FDB increased its mark-up of AWP from 20% to 25%

- No spreads above 30%
- Always "substantial sales" at WAC
- NDC 00085-1288 launched after 2003

			FDB	Medispan		within NDC9 solete/Inactive	Date of	Date
Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Inactive Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000851197	10/16/97	12/20/04	01/03/05	12/20/04	01/03/05	01/16/06	03/21/07
2	000851288	12/17/04					09/30/07	09/30/07

^{*} CMS reimbursement data for Q3 2003 for the NDC 00085-1197 appear to be inaccurate, resulting in an inflated Medicaid reimbursement amount for 2003

Nitro-Dur



Mo Liability Applying Judge Saris' Criteria

		1997	,		1998	1		1999)		2000	1		2001			2002	t		2003	3*
NDC-9	Spread	Sales at List	Reimb																		
000850819 ¹	25%	88%	\$309,129	31%	84%	\$433,875	26%	77%	\$511,236	26%	80%	\$598,261	30%	75%	\$759,510	32%	87%	\$832,733	30%	80%	\$31,689,039
000853305 ²	267%	64%	\$1,753,686	37%	64%	\$2,008,740	31%	53%	\$1,478,633	28%	61%	\$1,091,444	34%	51%	\$927,118	34%	61%	\$671,227	33%	70%	\$29,824,451
000853310 ³	27%	63%	\$6,731,892	31%	57%	\$5,317,243	27%	55%	\$4,427,585	28%	57%	\$3,517,504	32%	53%	\$3,214,457	34%	56%	\$2,338,895	31%	70%	\$44,373,245
0008533154	26%	64%	\$2,583,083	30%	58%	\$2,567,273	27%	59%	\$2,544,950	28%	61%	\$2,929,476	34%	50%	\$3,259,668	35%	64%	\$3,299,080	33%	83%	\$85,499,817
0008533205	26%	58%	\$7,115,906	29%	54%	\$5,667,424	26%	58%	\$4,633,276	27%	54%	\$3,742,477	32%	50%	\$3,412,451	33%	63%	\$2,504,104	31%	74%	\$89,755,500
000853330 ⁶	32%	62%	\$2,012,111	30%	56%	\$1,703,082	30%	56%	\$1,354,534	29%	59%	\$1,060,994	32%	51%	\$975,149	33%	69%	\$753,199	31%	85%	\$42,138,378

† On March 1, 2002, FDB increased its mark-up of AWP from 20% to 25%

			FDB	Medispan		within NDC9 solete/Inactive	Date of	Date
Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Inactive Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000850819	03/31/94					09/26/07	09/28/07
2	000853305	01/29/87	01/01/94	06/10/93			09/26/07	09/27/07
3	000853310	01/29/87					09/26/07	09/26/07
4	000853315	01/29/87					09/26/07	09/27/07
5	000853320	01/29/87					09/27/07	09/27/07
6	000853330	01/29/87					09/26/07	09/26/07

- Always "substantial sales" at WAC
- For all NDCs over the entire period, there is no instance in which the spread was above 30% for which sales at WAC were below 50%

^{*} CMS reimbursement data for Q3 2003 for Nitro-Dur appear to be inaccurate, resulting in an inflated Medicaid reimbursement amount for 2003

Normodyne



☑ No Liability Applying Judge Saris' Criteria

		1997	,		1998	3		1999)		2000			2001			2002			2003	
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb
0008502441	24%	95%	\$1,435,528	25%	95%	\$1,414,124	25%	86%	\$503,371	25%	85%	\$220,682	112%	88%	\$121,088						
000850362 ²	135%	6%	\$273	159%	9%	\$23	92%	5%	\$37	74%	13%	\$0	59%	16%	\$98	31%	9%	\$0		57%	\$0
000850438 ³	24%	95%	\$1,213,217	24%	95%	\$1,333,600	23%	84%	\$499,902	23%	92%	\$217,081	21%	80%	\$137,784						
0008507524	24%	93%	\$3,972,324	24%	94%	\$4,018,168	24%	83%	\$1,270,981	25%	83%	\$543,987	23%	65%	\$269,226						

- For 3 of 4 Normodyne NDCs, there is only one instance in which the spread was above 30% and there were always "substantial sales" at WAC
- NDC 00085-0362 is a syringe sold to non-AMP classes of trade such as hospitals, and only has \$410 in reimbursement for the entire seven year period (less than \$60 per year)

			FDB Obsolete	Medispan		within NDC9 colete/Inactive	Date of	Date
Foot- note	NDC-9	Date Added	Date of First NDC	Inactive Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000850244	05/30/85	05/17/02	05/17/02	05/17/02	05/17/02	02/20/02	02/20/02
2	000850362	01/12/89		02/11/04		02/11/04	09/03/02	05/15/03
3	000850438	08/24/84	05/17/02	05/17/02	05/17/02	05/17/02	01/02/02	02/27/02
4	000850752	08/24/84	05/17/02	05/17/02	05/17/02	05/17/02	02/08/02	02/08/02

3 of 4 Normodyne NDCs became obsolete in 2002

Peg Intron



Mo Liability Applying Judge Saris' Criteria

		1997			1998			1999			2000			2001	ı		2002	2†		200	3*
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb												
000851279 ¹													23%	97%	\$2,707,234	27%	94%	\$26,921,991	30%	67%	\$96,271,969
0008512912													23%	96%	\$2,846,975	27%	95%	\$12,741,334	30%	78%	\$39,813,013
0008512973																					
0008513044													23%	97%	\$3,465,090	27%	94%	\$29,417,253	30%	68%	\$99,783,667
0008513165																					
000851368 ⁶													23%	97%	\$1,200,435	27%	96%	\$2,570,608	29%	77%	\$4,735,400
000851370 ⁷																					

† On June 26, 2002, FDB increased its mark-up of AWP from 20% to 25%

Become Obsolete/Inactive FDB Medisnar Date of Date Obsolete Last Gross of Last Inactive Foot-Date of Date of Obsolete Date Inactive Date Sales to AMP Gross Sales NDC-9 Date Added note First NDC of Last NDC of Last NDC Classes of Trade Activity 000851279 01/31/01 09/27/07 09/28/07 01/31/01 09/26/07 09/26/07 000851297 02/02/04 09/27/07 09/27/07 000851304 01/31/01 09/27/07 09/27/07 000851316 02/02/04 09/26/07 09/27/07 000851368 01/31/01 09/27/07 09/27/07

000851370

02/02/04

If All NDCs within NDC9

Always "substantial sales" at WAC

No spreads above 30%

 Peg Intron was launched in 2001 and certain NDCs (00085-1297, 00085-1316, and 00085-1370) were launched after 2003

09/27/07

09/28/07

^{*} CMS reimbursement data for Q3 2003 for Peg Intron appear to be inaccurate, resulting in an inflated Medicaid reimbursement amount for 2003

Proventil



☑ No Liability Applying Judge Saris' Criteria

		199	7		1998	8		199	9		2000	0		200	1		2002	:†		2003	3 *
NDC-9	Spread	Sales at List	Reimb																		
000850208 ¹	41%	24%	\$853,204	28%	49%	\$398,001	24%	31%	\$229,289	29%	43%	\$132,990	30%	78%	\$61,759	42%	17%	\$34,864			
000850209 ²	53%	39%	\$2,288,209	27%	79%	\$1,558,894	24%	77%	\$1,410,649	26%	87%	\$1,097,478	41%	77%	\$1,018,508						
000850252 ³	22%	98%	\$19,828	20%	98%	\$15,220	22%	98%	\$12,954	7%	96%	\$9,607			\$2,170						
0008503154	72%	34%	\$80,989	16%	47%	\$49,950	19%	67%	\$33,247	26%	70%	\$16,342			\$13,261						
0008504315	24%	89%	\$8,567,156	23%	92%	\$7,909,894	23%	93%	\$7,252,845	24%	91%	\$6,372,039	25%	87%	\$5,640,062						
000850573 ⁶	21%	97%	\$34,101	23%	97%	\$26,022	22%	97%	\$27,469	14%	96%	\$22,836	26%	58%	\$15,312						
000850614 ⁷	26%	69%	\$10,455,169	23%	81%	\$5,099,432	23%	92%	\$3,853,856	24%	88%	\$2,553,479	23%	89%	\$2,055,022	30%	68%	\$1,560,694	28%	82%	\$6,204,148
0008511328	38%	83%	\$4,323,585	28%	81%	\$10,606,605	23%	87%	\$15,058,564	24%	88%	\$17,676,572	41%	51%	\$17,249,019	31%	95%	\$13,463,018	28%	93%	\$98,713,244
000851806 ⁹						·							·		·	·			28%	96%	\$73,284

† On February 1, 2002, FDB increased its mark-up of AWP from 20% to 25% for NDCs 00085-0614 and 00085-1132 and placed a 25% mark-up on NDC 00085-1806 when it was launched

- Judge Saris examined certain Proventil NDCs in the MDL (00085-020901, 00085-180601, and 00085-020802, 00085-133601) and found "no liability"
- The spread and sales at WAC analyses for the remaining NDCs yield even more compelling results
 - There is no period among these remaining NDCs during which the spread was above 30% for which sales at WAC were below 50%

^{*} CMS reimbursement data for Q3 2003 for Proventil appear to be inaccurate, resulting in an inflated Medicaid reimbursement amount for 2003

Proventil (cont.)



			FDB	Medispan		within NDC9 olete/Inactive	Date of	Date
Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Inactive Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000850208	02/19/87	06/24/03	06/24/03	06/24/03	06/24/03	12/13/02	03/30/03
2	000850209	02/19/87	10/01/02	10/01/02	10/01/02	10/01/02	10/18/02	10/18/02
3	000850252	01/01/82	05/17/02	05/17/02	05/17/02	05/17/02	11/22/00	01/03/01
4	000850315	09/12/85	01/01/02	01/01/02	01/01/02	01/01/02	06/04/01	06/12/01
5	000850431	06/25/87	05/17/02	05/17/02	05/17/02	05/17/02	08/07/07	08/07/07
6	000850573	01/01/82	05/17/02	05/17/02	05/17/02	05/17/02	10/08/01	11/06/01
7	000850614	01/01/82		02/24/06			09/25/07	09/27/07
8	000851132	10/16/96					09/30/07	09/30/07
9	000851806	10/01/02					09/25/07	09/25/07

- NDC 00085-0208 became functionally obsolete in Q3 2002
- The last gross sale to the AMP classes of trade for NDC 00085-0252 occurred in Q4 2000
- The last gross sale to the AMP classes of trade for NDC 00085-0315 occurred in Q2 2001
- The last gross sale to the AMP classes of trade for NDC 00085-0573 occurred in Q4 2001
- NDCs 00085-0209 and 00085-0431 became obsolete in 2002
- NDC 00085-1806 was launched in Q4 2002 and no analysis was done for that part year

Rebetol



		1997			1998			1999			2000			200)1		2002	2†		200	03*
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb															
000851194 ¹																29%	84%	\$37,171,116	32%	59%	\$135,983,786
0008513272																30%	80%	\$4,219,171	32%	71%	\$13,896,945
000851351 ³																29%	76%	\$14,265,646	33%	52%	\$39,898,740
0008513854																29%	89%	\$21,871,201	34%	51%	\$76,169,595

† On March 13, 2002, FDB increased its mark-up of AWP from 20% to 25%

- Spreads above 30% only after First DataBank had increased its mark-up of AWP from 20% to 25%, an occurrence over which Schering had no control
- Always "substantial sales" at WAC

			FDB	Medispan		within NDC9 solete/Inactive	Date of	Date
Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Inactive Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000851194	10/04/01					09/25/07	09/25/07
2	000851327	10/04/01					09/20/07	09/20/07
3	000851351	10/04/01					09/25/07	09/25/07
4	000851385	10/04/01					09/25/07	09/25/07

- There is no period during which the spread was above 30% for which sales at WAC were below 50%
- Rebetol was launched in Q4 2001 and no analysis was done for that part year

^{*} CMS reimbursement data for Q3 2003 for the Rebetol appear to be inaccurate, resulting in an inflated Medicaid reimbursement amount for 2003

Rebetron



		1997			1998			199	9		2000)		200	1		2002	2		2003	
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb
000851236 ¹				23%	n/d◊	\$162,635	23%	84%	\$1,868,846	24%	76%	\$4,431,484	25%	42%	\$3,623,780	16%	60%	\$1,071,153	21%	60%	\$573,803
0008512412				23%	n/d◊	\$1,734,604	23%	89%	\$12,325,731	25%	72%	\$23,536,058	26%	48%	\$18,047,905						
000851258 ³							23%	87%	\$12,626,252	25%	76%	\$40,940,695	26%	46%	\$45,746,989	23%	50%	\$17,561,342	21%	41%	\$4,939,491

[♦] FDB has no listed WAC during 1998

- No spreads above 30%
- "Substantial sales" at WAC in most years

			FDB	Medispan		within NDC9 olete/Inactive	Date of	Date
Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Inactive Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000851236	06/11/98	04/15/05	02/24/06	04/15/05	02/24/06	10/22/04	11/30/04
2	000851241	06/11/98	08/20/02	02/24/06	08/20/02	02/24/06	12/03/02	05/08/03
3	000851258	07/14/98	04/15/05	02/24/06	04/15/05	02/24/06	09/30/04	03/15/05

- NDCs 00085-1236 and 00085-1241 were launched in Q2 1998
- NDC 00085-1258 was launched in Q3 1998 and no analysis was done on that part year
- NDC 00085-1241 became obsolete in 2002

Sebizon



		1997			1998 Sales			1999			2000			2001			2002			2003	
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb									
000850600 ¹	22%	99%	\$14,537	23%	99%	\$13,320	23%	100%	\$13,011	22%	99%	\$10,206									

- No spreads above 30%
- Always "substantial sales" at WAC
- The last gross sale to the AMP classes of trade for Sebizon occurred in Q4 2000

			FDB Obsolete	Medispan Inactive		within NDC9 solete/Inactive	Date of Last Gross	Date of Last
Foot- note	NDC-9	Date Added	Date of First NDC	Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Sales to AMP Classes of Trade	Gross Sales Activity
1	000850600	01/01/82	08/17/05	02/24/06	08/17/05	02/24/06	10/16/00	10/16/00

Solganal



		1997			1998			1999			2000			2001			2002			2003	
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb												
00085046 ¹	23%	83%	\$517,818	23%	78%	\$223,867	23%	86%	\$170,176	23%	85%	\$212,237	24%	78%	\$190,607						

- No spread above 30%
- Always "substantial sales" at WAC
- Solganal became obsolete in 2002

			FDB Obsolete	Medispan Inactive		within NDC9 olete/Inactive	Date of Last Gross	Date of Last
Foot- note	NDC-9	Date Added	Date of First NDC	Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Sales to AMP Classes of Trade	Gross Sales Activity
1	000850460	01/01/82	05/17/02	05/17/02	05/17/02	05/17/02	10/02/02	10/02/02

Temodar



☑ No Liability Applying Judge Saris' Criteria

		1997			1998			1999			2000)		2001			2002	t		2003	}
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb									
000851244 ¹										23%	97%	\$255,587	24%	94%	\$524,876	30%	88%	\$1,040,851	28%	87%	\$1,273,252
000851248 ²										23%	97%	\$37,374	25%	95%	\$61,122	30%	93%	\$103,058	28%	88%	\$172,201
000851252 ³										23%	95%	\$1,050,364	25%	92%	\$1,720,749	30%	90%	\$2,611,071	28%	83%	\$5,768,011
0008512594										23%	96%	\$2,520,401	24%	93%	\$4,671,103	30%	92%	\$7,271,833	28%	92%	\$8,989,957

† On March 1, 2002, FDB increased its mark-up of AWP from 20% to 25%

- No spreads above 30%
- Always "substantial sales" at WAC
- Judge Saris examined Temodar in the MDL and found no liability

			FDB Observator	Medispan	If All NDCs of Become Obs		Date of	Date
Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Inactive Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000851244	08/19/99					08/01/07	09/19/07
2	000851248	08/19/99					09/26/07	09/28/07
3	000851252	08/19/99					08/10/07	09/10/07
4	000851259	08/19/99					06/12/07	08/27/07

 Temodar was launched in Q2 1999 and no analysis was done on that part year

Theo-Dur



		1997			1998	3		1999	9		2000)		2001			2002			2003	
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb									
000850381 ¹																					
0008504872	56%	70%	\$137,063	33%	74%	\$129,730	23%	84%	\$71,115	25%	91%	\$32,859									
000850584 ³	33%	38%	\$1,772,568	23%	82%	\$1,724,759	24%	82%	\$1,222,041	23%	81%	\$1,032,670									
0008506204																					
0008508065	31%	93%	\$471,546	23%	94%	\$334,889	23%	92%	\$263,317	20%	91%	\$189,182									
000850875 ⁶																					
000850928 ⁷																					
0008509338	35%	39%	\$1,190,000	24%	76%	\$1,125,938	24%	77%	\$741,281	27%	82%	\$632,849									

- Only a handful of spreads above 30%
- "Substantial sales" at WAC for all years except in 1997 for two NDCs
- There are only two periods during which the spread was above 30% for which sales at WAC were below 50%

Theo-Dur (cont.)



			FDB	Medispan		within NDC9 solete/Inactive	Date of	Date
Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Inactive Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000850381	01/22/87	01/25/95	02/01/95	01/25/95	02/01/95	11/21/95	05/14/96
2	000850487	01/22/87	06/30/01	06/30/01	06/30/01	06/30/01	09/29/00	10/16/00
3	000850584	01/22/87	06/30/01	06/30/01	06/30/01	06/30/01	02/11/02	04/22/02
4	000850620	01/22/87	01/25/95	01/25/95	01/25/95	01/25/95	04/06/95	07/06/95
5	000850806	08/06/87	06/30/01	06/30/01	06/30/01	06/30/01	03/06/02	03/08/02
6	000850875	01/29/87	01/25/95	02/01/95	01/25/95	02/01/95	01/17/96	02/14/96
7	000850928	01/22/87	01/25/95	02/01/95	01/25/95	02/01/95	11/28/95	12/06/95
8	000850933	01/22/87	06/30/01	06/30/01	06/30/01	06/30/01	11/23/01	03/08/02

- NDCs 00085-0381, 00085-0620, 00085-0875, 00085-0928 were obsolete before 1997
- All Theo-Dur NDCs were obsolete by June 2001

Trinalin



		1997	,		1998			1999			2000			2001			2002			2003	
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb
000850703 ¹	23%	96%	\$1,116,639	23%	96%	\$953,412	23%	96%	\$808,896	23%	95%	\$639,977	25%	89%	\$672,802	23%	91%	\$465,397			

- No spreads above 30%
- Always "substantial sales" at WAC
- Trinalin became obsolete in 2003

			FDB Obsolete	Medispan Inactive		within NDC9 solete/Inactive	Date of Last Gross	Date of Last
Foot- note	NDC-9	Date Added	Date of First NDC	Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Sales to AMP Classes of Trade	Gross Sales Activity
1	000850703	01/01/82	04/14/03	04/14/03	04/14/03	04/14/03	07/01/03	09/24/03

Vancenase



		1997	7		1998	3		199	9		200	0		2001			2002			2003	
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List		Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb
0008500411	25%	40%	\$146,635	27%	43%	\$149,863	24%	42%	\$196,708			\$67,971									
0008502592	28%	74%	\$4,437,873																		
0008506493	25%	65%	\$4,785,341	24%	64%	\$5,261,149	23%	71%	\$5,049,094	27%	67%	\$2,488,964	33%	53%	\$1,815,549						
0008510494	28%	60%	\$15,663,040	25%	83%	\$20,794,184	23%	92%	\$18,087,887	23%	91%	\$14,351,814			\$4,873,713						

- Only a single occurrence of a spread above 30%
- There is no period during which the spread was above 30% for which sales at WAC were below 50%

Vancenase (cont.)



- NDC 00085-0041 became functionally obsolete in Q1 2000
- NDC 00085-1049 became functionally obsolete in Q1 2001
- NDC 00085-0649 became functionally obsolete in Q4 2001
- NDC 00085-0259 became obsolete in 1998
- All Vancenase NDCs were obsolete by June 2002

			FDB	Medispan		within NDC9 colete/Inactive	Date of	Date
Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Inactive Date of First NDC	Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000850041	01/01/82	02/01/01	02/01/01	05/21/01	04/16/01	01/25/00	01/26/01
2	000850259	12/17/87	08/11/98	08/01/98	08/11/98	08/01/98	09/01/98	09/22/98
3	000850649	07/20/92	06/01/02	06/01/02	06/01/02	06/01/02	01/24/02	11/06/02
4	000851049	06/27/96	05/17/02	05/17/02	05/17/02	05/17/02	03/08/02	11/22/02

Vanceril



		199	7		1998	3		199	9		2000)		2001	I		2002			2003	
NDC-9	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb	Spread	Sales at List	Reimb												
000850736 ¹	24%	77%	\$18,019,586	24%	80%	\$16,466,470	23%	77%	\$16,617,804	26%	72%	\$15,114,086	25%	61%	\$11,960,009						
0008511122	25%	93%	\$1,198,786	24%	91%	\$2,519,978	24%	84%	\$6,922,621			\$506,758			\$61,739						

- No spreads above 30%
- Always "substantial sales" at WAC
- NDC 00085-1112 became functionally obsolete in Q1 2000
- The last Vanceril NDC was declared obsolete in 2002

			FDB	Medispa n	FDB Inactive bsolete Date of First	If All NDCs v Become Obs		Date of	Date
Foot- note	NDC-9	Date Added	Obsolete Date of First NDC	Obsolete Date of		Obsolete Date of Last NDC	Inactive Date of Last NDC	Last Gross Sales to AMP Classes of Trade	of Last Gross Sales Activity
1	000850736	01/01/82	10/01/02	10/01/02	10/01/02	10/01/02	03/25/03	04/03/07	
2	000851112	12/26/96	05/17/02	05/17/02	05/17/02	05/17/02	05/02/03	05/02/03	

Exhibit B

VEN-A-CARE TO AMEND THE COMPLAINT AS FOLLOWS:

- 1. Insert NEW paragraph after current Paragraph 75: Through its investigation and through its litigation in the instant action and in related state actions, Ven-A-Care has reviewed the DEFENDANTS' price reports to the Price Publications for the DEFENDANTS' drug products reimbursed by the states' Medicaid programs. Specifically, Ven-A-Care has investigated the Specified Drugs in Exhibit E and has alleged that the DEFENDANTS knowingly reported false, inflated prices for the Specified Drugs in Exhibit E. Ven-A-Care has investigated additional drugs marketed by the DEFENDANTS during the relevant time period. Those additional drugs are hereinafter referred to as "Schering Brand Drugs" and are listed in Exhibit F. Ven-A-Care has determined that the states' Medicaid programs did not incur substantial damages for the Schering Brand Drugs because the DEFENDANTS did not materially misstate the drug price report for those drugs. Ven-A-Care has determined that the states' Medicaid programs did not incur substantial damages for the Schering Brand Drugs because the DEFENDANTS caused AWPs to be reported that were within 25% of the Wholesaler's Acquisition Cost (subject to at most a 5% discount off of WAC) and thus did not materially misstate the drug price report for those drugs.
- 2. Attach Exhibits E and F (as attached hereto)

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DRUG	NDC
Albuterol	59930-1560-01
Albuterol	59930-1560-02
Albuterol	59930-1647-02
Albuterol Sulfate	59930-1500-06
Albuterol Sulfate	59930-1500-08
Albuterol Sulfate	59930-1510-05
Albuterol Sulfate	59930-1515-04
Albuterol Sulfate	59930-1517-01
Albuterol Sulfate	59930-1517-02
Albuterol Sulfate	59930-1520-01
Albuterol Sulfate	59930-1520-02
Albuterol Sulfate	59930-1530-01
Albuterol Sulfate	59930-1530-02
Amoxicillin	59930-1573-01
Amoxicillin	59930-1573-02
Amoxicillin	59930-1573-03
Amoxicillin	59930-1611-02
Amoxicillin	59930-1611-03
Betamethasone	59930-1575-01
Betamethasone	59930-1575-02
Betamethasone	59930-1575-03
Captopril	59930-1655-01
Captopril	59930-1655-03
Captopril	59930-1656-01
Cholestryamine	59930-1638-01
Cholestryamine	59930-1638-02

DRUG	NDC
Cimetidine	59930-1800-01
Cimetidine	59930-1801-01
Cimetidine	59930-1801-02
Cimetidine	59930-1801-03
Cimetidine	59930-1802-01
Cimetidine	59930-1802-02
Cimetidine	59930-1802-03
Cimetidine	59930-1803-01
Cimetidine	59930-1803-02
Clotrimazole	59930-1503-01
Clotrimazole	59930-1503-02
Clotrimazole	59930-1542-01
Clotrimazole	59930-1570-01
Clotrimazole	59930-1570-02
Clotrimazole	59930-1570-03
Clotrimazole	59930-1570-09
Cromolyn Sodium	59930-1509-01
Cromolyn Sodium	59930-1509-02
Flurbiprofen	59930-1771-01
Flurbiprofen	59930-1772-01
Glyburide	59930-1592-01
Glyburide	59930-1639-01
Glyburide	59930-1622-01
Glyburide	59930-1639-02
Glyburide	59930-1639-03
Griseofulvin	59930-1620-01

DRUG	NDC
Griseofulvin	59930-1621-01
Griseofulvin	59930-1624-01
ISMN	59930-1502-01
ISMN	59930-1549-01
ISMN	59930-1587-01
ISMN	59930-3094-01
ISMN	59930-3144-03
ISMN	59930-3605-01
Labetalol HCL	59930-1602-01
Labetalol HCL	59930-1602-02
Labetalol HCL	59930-1602-03
Labetalol HCL	59930-1602-04
Labetalol HCL	59930-1636-01
Labetalol HCL	59930-1636-02
Labetalol HCL	59930-1636-03
Labetalol HCL	59930-1636-04
Labetalol HCL	59930-1653-01
Labetalol HCL	59930-1653-02
Labetalol HCL	59930-1653-03
Mexiletine	59930-1686-01
Mexiletine	59930-1685-01
Mexiletine	59930-1687-01
Mometasone Furoate	59930-1526-01
Mometasone Furoate	59930-1526-02
Mometasone Furoate	59930-1547-03
Oxaprozin	59930-1508-01

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DRUG	NDC
Oxaprozin	59930-1508-02
Perphenazine	59930-1600-01
Perphenazine	59930-1603-01
Perphenazine	59930-1605-01
Perphenazine	59930-1610-01
Potassium Chloride	59930-1714-01
Potassium Chloride	59930-1714-02
Potassium Chloride	59930-1714-03
Potassium Chloride	59930-1715-01
Ribavirin	59930-1523-01
Ribavirin	59930-1523-02
Ribavirin	59930-1523-03
Ribavirin	59930-1523-04
Selegiline	59930-1537-01
Sodium Chloride	59930-1609-01
Sodium Chloride	59930-1609-02
Sulcrafate Tablets	59930-1532-01
Sulcrafate Tablets	59930-1532-02
Theophylline	59930-1650-01
Theophylline	59930-1650-02
Theophylline	59930-1650-03
Theophylline	59930-1660-01
Theophylline	59930-1660-02
Theophylline	59930-1660-03
Theophylline	59930-1670-01
Theophylline	59930-1670-02

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Theophylline	59930-1680-01
Theophylline	59930-1670-03
DRUG	NDC

DRUG	NDC
Cedax	00085-0691-01
Cedax	00085-0691-02
Cedax	00085-0691-03
Cedax	00085-0777-01
Cedax	00085-0777-02
Cedax	00085-0777-03
Cedax	00085-0777-04
Cedax	00085-0834-01
Cedax	00085-0834-03
Celestone Soluspan	00085-0011-01
Celestone Soluspan	00085-0011-05
Celestone Soluspan	00085-0566-05
Celestone Soluspan	00085-0942-05
Clarinex	00085-1264-01
Clarinex	00085-1264-02
Clarinex	00085-1264-03
Clarinex	00085-1264-04
Clarinex	00085-1280-01
Clarinex	00085-1334-01
Claritin	00085-0458-01
Claritin	00085-0458-03
Claritin	00085-0458-04
Claritin	00085-0458-05
Claritin	00085-0458-06
Claritin	00085-0612-02
Claritin	00085-1128-02

DRUG	NDC
Claritin	00085-1223-01
Claritin D	00085-0635-01
Claritin D	00085-0635-04
Claritin D	00085-0635-05
Claritin D	00085-0640-01
Claritin D	00085-0640-02
Claritin D	00085-1233-01
Claritin D	00085-1233-02
Diprolene	00085-0517-01
Diprolene	00085-0517-02
Diprolene	00085-0517-04
Diprolene	00085-0575-02
Diprolene	00085-0575-03
Diprolene	00085-0575-05
Diprolene	00085-0634-01
Diprolene	00085-0634-02
Diprolene	00085-0634-03
Diprolene	00085-0962-01
Diprolene	00085-0962-02
Diprosone	00085-0475-06
Diprosone	00085-0853-02
Diprosone	00085-0853-03
Elocon	00085-0370-01
Elocon	00085-0370-02
Elocon	00085-0567-01
Elocon	00085-0567-02

DRUG	NDC
Elocon	00085-0854-01
Elocon	00085-0854-02
Eulexin	00085-0525-03
Eulexin	00085-0525-04
Eulexin	00085-0525-05
Eulexin	00085-0525-06
Foradil	00085-1401-01
Foradil	00085-1402-01
Fulvicin	00085-0496-03
Fulvicin	00085-0496-06
IMDUR	00085-1153-03
IMDUR	00085-1153-04
IMDUR	00085-4110-01
IMDUR	00085-4110-03
IMDUR Tablet	00085-3306-01
IMDUR Tablet	00085-3306-03
Intron A	00085-0120-02
Intron A	00085-0120-03
Intron A	00085-0120-04
Intron A	00085-0120-05
Intron A	00085-0285-02
Intron A	00085-0539-01
Intron A	00085-0571-02
Intron A	00085-0571-06
Intron A	00085-0647-03
Intron A	00085-0647-04

DRUG	NDC
Intron A	00085-0647-05
Intron A	00085-0689-01
Intron A	00085-0769-01
Intron A	00085-0923-01
Intron A	00085-0953-01
Intron A	00085-1110-01
Intron A	00085-1133-01
Intron A	00085-1168-01
Intron A	00085-1179-01
Intron A	00085-1179-02
Intron A	00085-1184-01
Intron A	00085-1184-02
Intron A	00085-1191-01
Intron A	00085-1191-02
Intron A	00085-1235-01
Intron A	00085-1242-01
Intron A	00085-1254-01
K-Dur	00085-0263-01
K-Dur	00085-0263-81
K-Dur	00085-0787-01
K-Dur	00085-0787-06
K-Dur	00085-0787-10
K-Dur	00085-0787-81
Lotrimin	00085-0182-02
Lotrimin	00085-0182-04
Lotrimin	00085-0613-02

DRUG	NDC
Lotrimin	00085-0613-03
Lotrimin	00085-0613-04
Lotrimin	00085-0613-05
Lotrimin	00085-0707-02
Lotrisone	00085-0809-01
Lotrisone	00085-0924-01
Lotrisone	00085-0924-02
Nasonex	00085-1197-01
Nasonex	00085-1288-01
Nitro-Dur	00085-0819-30
Nitro-Dur	00085-0819-35
Nitro-Dur	00085-3305-10
Nitro-Dur	00085-3305-30
Nitro-Dur	00085-3305-35
Nitro-Dur	00085-3310-30
Nitro-Dur	00085-3310-35
Nitro-Dur	00085-3315-30
Nitro-Dur	00085-3315-35
Nitro-Dur	00085-3320-30
Nitro-Dur	00085-3320-35
Nitro-Dur	00085-3330-30
Nitro-Dur	00085-3330-35
Normodyne	00085-0244-04
Normodyne	00085-0244-05
Normodyne	00085-0244-07
Normodyne	00085-0244-08

DRUG	NDC
Normodyne	00085-0362-08
Normodyne	00085-0438-03
Normodyne	00085-0438-05
Normodyne	00085-0752-04
Normodyne	00085-0752-05
Normodyne	00085-0752-07
Normodyne	00085-0752-08
Peg-Intron	00085-1279-01
Peg-Intron	00085-1291-01
Peg-Intron	00085-1297-01
Peg-Intron	00085-1297-02
Peg-Intron	00085-1304-01
Peg-Intron	00085-1316-01
Peg-Intron	00085-1368-01
Peg-Intron	00085-1370-01
Peg-Intron	00085-1370-02
Proventil	00085-0208-02
Proventil	00085-0209-01
Proventil	00085-0252-02
Proventil	00085-0252-03
Proventil	00085-0315-02
Proventil	00085-0431-02
Proventil	00085-0431-03
Proventil	00085-0431-04
Proventil	00085-0573-02
Proventil	00085-0573-03

DRUG	NDC
Proventil	00085-0614-02
Proventil	00085-0614-03
Proventil	00085-1132-01
Proventil	00085-1336-01
Proventil	00085-1806-01
Rebetol	00085-1194-03
Rebetol	00085-1327-04
Rebetol	00085-1351-05
Rebetol	00085-1385-07
Rebetron	00085-1236-01
Rebetron	00085-1236-02
Rebetron	00085-1236-03
Rebetron	00085-1241-01
Rebetron	00085-1241-02
Rebetron	00085-1241-03
Rebetron	00085-1258-01
Rebetron	00085-1258-02
Rebetron	00085-1258-03
Sebizon	00085-0600-05
Solganal	00085-0460-03
Temodar	00085-1244-01
Temodar	00085-1244-02
Temodar	00085-1248-01
Temodar	00085-1248-02
Temodar	00085-1252-01
Temodar	00085-1252-02

DRUG	NDC
Temodar	00085-1259-01
Temodar	00085-1259-02
Theo-Dur	00085-0381-01
Theo-Dur	00085-0487-01
Theo-Dur	00085-0487-05
Theo-Dur	00085-0487-10
Theo-Dur	00085-0487-81
Theo-Dur	00085-0584-01
Theo-Dur	00085-0584-05
Theo-Dur	00085-0584-10
Theo-Dur	00085-0584-50
Theo-Dur	00085-0584-81
Theo-Dur	00085-0620-01
Theo-Dur	00085-0806-01
Theo-Dur	00085-0806-81
Theo-Dur	00085-0875-01
Theo-Dur	00085-0928-01
Theo-Dur	00085-0933-01
Theo-Dur	00085-0933-05
Theo-Dur	00085-0933-10
Theo-Dur	00085-0933-50
Theo-Dur	00085-0933-81
Trinalin	00085-0703-04
Vancenase	00085-0041-06
Vancenase	00085-0041-11
Vancenase	00085-0259-02

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DRUG	NDC
Vancenase	00085-0649-02
Vancenase	00085-1049-01
Vanceril	00085-0736-04
Vanceril	00085-1112-01
Vanceril	00085-1112-03

Exhibit C

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

In re:) MDL No. 1456
) Civil Action No. 01-12257-PBS
PHARMACEUTICAL INDUSTRY	Subcategory No. 06-11337
AVERAGE WHOLESALE PRICE)
LITIGATION) Hon. Patti B. Saris
)
)
THIS DOCUMENT RELATES TO:)
THIS DOCUMENT RELATES TO:)
United States ex rel Ven-A-Care of the	,)
Florida Keys, Inc. v. Schering Corporation,)
Schering-Plough Corporation and	
Warrick Pharmaceuticals Corporation	
Civil Action No. 09-CV-10547)
United States ex rel Ven-A-Care of the	
Florida Keys, Inc. v. Schering Corporation,)
Schering-Plough Corporation and	,)
Warrick Pharmaceuticals Corporation	,)
Civil Action No. 00-10698	,)

ORDER APPROVING SETTLEMENT AND DISMISSAL WITH PREJUDICE OF SCHERING-PLOUGH CORPORATION, SCHERING CORPORATION AND WARRICK PHARMACEUTICALS CORPORATION

WHEREAS, this is a *qui tam* action brought by the Relator on behalf of the United States pursuant to the False Claims Act (31 U.S.C. § 3729, *et. seq*) with respect to which the United States has declined to proceed and, accordingly, the Relator has proceeded with the action pursuant to 31 U.S.C. § 3730(c)(3); and

WHEREAS, the parties to this case have reached a settlement resolving all claims that Schering and Warrick knowingly set, reported, and maintained or caused to be set, reported and maintained false, fraudulent, and inflated Average Wholesale Prices, Suggested List Prices, Wholesale Acquisition Costs, Wholesale Net Prices, Direct Prices, Wholesale Direct Prices, and

Net Direct Prices, among others, as more fully described in the Settlement Agreement ("Covered Conduct"); and

WHEREAS, based on the terms and conditions set forth in their Settlement Agreement, the parties have asked the Court to enter an order approving the settlement and dismissing with prejudice all claims asserted or that could have been asserted on behalf of the United States against the Schering-Plough Corporation, Schering Corporation, or Warrick Pharmaceuticals Corporation (collectively, the "Schering Defendants") in the above-captioned matters related to or concerning the Covered Conduct as defined in Preamble Paragraph II.F of the Settlement Agreement; and

WHEREAS, the allegations of the Amended Complaint relate to both brand and generic drugs, but the settlement proceeds are confined to payments relating to generic drugs. As to brand drugs, the Settlement is conditioned on a determination by the Court, based upon its experience in the AWP MDL, that it is reasonable and appropriate to conclude that there is no basis for alleging that a false statement was made about the inflation of a brand drug's AWP for Medicaid reimbursement purposes where the AWP for a brand drug falls within the formulaic range of up to 130% of the price generally and currently paid by the wholesaler; and

WHEREAS, the Court is required to determine that, under the circumstances, it is fair, adequate, and reasonable for the Relator to settle this *qui tam* action on behalf of the United States; and

WHEREAS, the Settlement is conditioned upon an independent review by the Court of the analyses set forth in Exhibit A to the Settlement Agreement; and the Court has determined that, under the circumstances, it is appropriate for the Court to conduct the review and make the determination requested by the Parties; and WHEREAS, the settlement also includes the settlement and dismissal with prejudice of *qui tam* actions brought by the Relator on behalf of the States of California and Florida pursuant to their respective state false claims acts and alleging conduct similar to the Covered Conduct specified in the Settlement Agreement, and, accordingly, the Relator, the Schering Defendants, the State of California, and the State of Florida have entered into the following agreements, which have been disclosed to the Court and, with respect to which, the Relator, the Schering Defendants, the State of California, and the State of Florida have requested that the Court exercise and retain jurisdiction in order to enable the resolution of this action and the related state actions:

- The Settlement Agreement between the State of Florida, the Relator and the Schering Defendants ("the Florida Settlement Agreement");
- 2.) The Settlement Agreement between the State of California, the Relator and the Schering Defendants ("the California Settlement Agreement");
- 3.) The Escrow Agreement between the State of Florida, the State of California, the Relator and the Schering Defendants ("the Escrow Agreement");
- 4.) The Allocation Agreement Between the Relator, the State of California and the State of Florida ("the Allocation Agreement"); and

WHEREAS, in accordance with the Settlement Agreement, the Schering Defendants have deposited the sum of Fifty-Five Million Dollars (\$55,000,000) to be held pursuant to the terms of the Escrow Agreement, and said amount is intended to resolve claims of the Relator, the State of Florida, the State of California, and those claims asserted on behalf of the United States; and

WHEREAS, the allocation of this sum has further been agreed to, pursuant to the Allocation Agreement, by the Relator and by States of Florida and California, through their

Attorneys General who have intervened in their respective states' actions, without any involvement by the Schering Defendants, and without their knowledge of the agreed-upon allocation, but whereas the United States is not a party to the Allocation Agreement; and

WHEREAS, the Parties stipulate that, pursuant to 31 U.S.C. § 3730(d), the Relator has a claim to an award based on a percentage of the proceeds to the United States of the Settlement, in an amount to be determined by the Court after the dismissal with prejudice of the Schering Defendants or pursuant to a separate agreement with the United States, and the Relator and its counsel shall be entitled to expenses, attorneys' fees, and costs in the amount of <a href="[to be inserted in final by Relators' counsel in accordance with the separate Allocation Agreement Between the Relator, the State of California and the State of Floridal, which amount shall be paid in accordance with the terms of the Settlement Agreement, the Florida Settlement Agreement, the California Settlement Agreement, the Escrow Agreement, and the Allocation Agreement; and

WHEREAS, it is may be necessary for the Court to retain jurisdiction over these matters after the dismissal with prejudice of the Schering Defendants to resolve the issue of allocation of the proceeds of the settlement between the State of Florida, the State of California, the Relator, and the United States, and the issue of the amount of the Relator's award to be paid from the proceeds of the settlement allocated to the United States; and

WHEREAS, this Court has reviewed the Settlement Agreement and, in particular Paragraph III.6 and Exhibit A thereto.

FINDINGS

Based in part on its extensive background obtained through the Average Wholesale Price Multi-District Litigation for the past eight years, and the evidence presented by the Parties, the Court makes the following factual findings, which form the basis for the Court's determination that the settlement is fair, adequate, and reasonable under all of the circumstances and that the

Court can and should retain jurisdiction over the matters requested herein in order to enable the Parties to effectuate their Settlement:

As to the Schering Defendants AWPs and WACs

- 1. Beginning in 1984, the Office of the Inspector General for the Department of Health and Human Services ("OIG") began publishing reports that quantified the discount off AWP at which, on average, pharmacies purchased brand drugs. These OIG reports were regularly distributed to state Medicaid programs. The OIG's 1984 report, for example, indicated that pharmacies then purchased brand drugs dispensed to Medicaid beneficiaries, on average, at about 16% below AWP. An October 1989 OIG report made very similar findings pharmacies were then purchasing brand drugs at, on average, 15.5% below AWP.
- 2. Consistent with the Court's finding made following the MDL bench trial that "government and industry were well aware by the late 1990's that there was a 20 to 25 percent spread" between published AWPs and WACs, see In re Pharm. Indus. Avg. Wholesale Price Litig., 491 F. Supp. 2d 20, 32 (D. Mass. 2007), the Court finds that it has long been understood that, historically, the AWPs reported by the national drug pricing compendia (i.e., FDB Bluebook, Redbook, and Medispan) for brand drugs typically represented an industry-wide, standard, formulaic mark-up of 20% or 25% over the wholesale acquisition cost or WAC for that drug. Furthermore, the Court finds that it was widely understood in the industry, by the early 1990's, that some limited discounting off of WAC (typically, 2% to 5%) was generally available for brand drugs. See id. at 76; see also In re Pharm. Indus. Avg. Wholesale Price Litig., 520 F. Supp. 2d 267, 272 (D. Mass. 2007).
- 3. Accordingly, the Court finds that government payors, such as Medicaid, did not reasonably consider published AWPs that were generally within 30% of the average selling price for that drug (measured, conservatively, by Average Manufacturers Price or AMP calculated in

accordance with all applicable HCFA/CMS regulations) to constitute a false or fraudulent statement, or to be misleading, deceptive or unfair. Moreover, consistent with this Court's findings made in its June 2007 decision, the Court finds that an "isolated, anomalous occurrence" of a spread greater than 30%, even one of "significant magnitude," does not give rise to liability. *See In re Pharm. Indus. Avg. Wholesale Price Litig.*, 491 F. Supp. 2d at 108.

- 4. Similarly, consistent with the Court's findings in the MDL that, "if more than 50 percent of all sales were made at or about the list price" or WAC (defined to mean within 5% of WAC), then "the list price will not be deemed fictitious," *id.* at 102, 105; *see also In re Pharm. Indus. Avg. Wholesale Price Litig.*, 520 F. Supp. 2d at 272, the Court finds, in the context of evaluating the fairness of the proposed settlement, that governmental payors could not have reasonably considered the published WAC for a brand drug where substantial sales were made at WAC (*i.e.*, more than 50% of a drug's sales occurred within 5% of WAC) to constitute a false or fraudulent statement, or to be misleading, deceptive or unfair. Furthermore, the Court finds that governmental payors could not have reasonably considered AWPs derived based on widely-known and industry-standard 20% or 25% mark-ups from such WACs to be a false or fraudulent statement, and are not misleading, deceptive, or unfair.
- 5. In connection with approving this settlement and entering an order dismissing the Schering Defendants from this case with prejudice, the Court received and reviewed the Settlement Agreement, including in particular Exhibit A thereto, and the Court finds that none of the WACs or AWPs for the Schering-brand drugs analyzed in Exhibit A to the Settlement Agreement constituted false or fraudulent statements, or were misleading, deceptive, or unfair.

As to the Reasonableness and Fairness of the Settlement

6. The fraudulent practice that Ven-A-Care alleges to have revealed to the government, and upon which its action is based, was the previously unknown manipulation and

inflation of reported AWPs and WACs by certain drug manufacturers that caused government programs, such as Medicaid, to set drug ingredient cost reimbursement amounts for certain drugs at levels substantially outside of this historic and generally understood relationship of those terms to the actual transaction prices in the marketplace.

7. In settling this case on behalf of the United States, Ven-A-Care has applied a "30% yardstick" similar to that applied by the Court, *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 491 F. Supp.2d 20, 32 (D. Mass. 2007), such that it has not sought to recover proceeds arising from Medicaid reimbursement for the Schering Defendants' brand drugs where AWP did not regularly exceed the average selling price of the drug (measured, conservatively, by AMP) by more than 30%. The "yardstick" approach applied by Ven-A-Care would also screen out brand drugs where the AWP was no more than 25% above a non-fictitious WAC and would accept a WAC as being "non-fictitious" for settlement purposes where it was reported in an amount that was discounted, if at all, only by nominal prompt-pay and similar discounts and was no more than 5% above the drug's average selling price. Under the circumstances, the Court finds this approach to the settlement of this *qui tam* action under the False Claims Act to be reasonable and fair.

As to the Retention of Jurisdiction to Resolve Allocation, Fee, and Other Issues

8. Based on the foregoing, all claims asserted or that could have been asserted on behalf of the United States against the Schering-Plough Corporation, the Schering Corporation, or the Warrick Pharmaceuticals Corporation in the above-captioned matters related to or concerning the Covered Conduct as defined in Preamble Paragraph II.F of the Settlement Agreement are hereby dismissed with prejudice, and the Schering Defendants are hereby dismissed from these actions.

9. Nevertheless, because the Schering Defendants have deposited the sum of \$55,000,000, to be held pursuant to the terms of the Escrow Agreement, and said amount is intended to resolve claims on behalf of the Relator, the State of Florida, the State of California and the United States, and because the allocation of this sum has further been agreed to, pursuant to the Allocation Agreement, by the Relator and by States of Florida and California, through their Attorneys General who have intervened in their respective states' actions, but the United States is not a party to the Allocation Agreement, the Court finds that it is necessary and appropriate for the Court to retain jurisdiction over the Allocation Agreement and Escrow Agreement pending further proceedings to determine whether the United States will consent to the allocations proposed by the Allocation Agreement and, if not, for the Court to determine how the settlement proceeds should be allocated in accordance with 31 U.S.C § 3730 and other applicable law.

NOW THEREFORE, based on the foregoing, this Court finds that the settlement is fair, adequate, and reasonable under all of the circumstances. Accordingly, all claims asserted or that could have been asserted on behalf of the United States against the Schering-Plough Corporation, the Schering Corporation, or the Warrick Pharmaceuticals Corporation in the above-captioned matters related to or concerning the Covered Conduct as defined in Preamble Paragraph II.F of the Settlement Agreement are hereby dismissed with prejudice. This Court shall remain a court of competent jurisdiction and shall retain continuing jurisdiction for purposes of enforcing the terms of the Settlement Agreement and all releases provided for therein, as well as the California and Florida Settlement Agreements, including for purposes of issuing an injunction in protection of the Court's jurisdiction to enforce the terms, conditions, and releases provided for in those settlement agreements. The Court shall also retain jurisdiction over the Allocation Agreement and Escrow Agreement pending further proceedings to determine whether the United States will

consent to the allocations proposed by the Allocation Agreement and, if not, for the Court to determine how the settlement proceeds should be allocated, and what award or awards should be paid to the Relator, in accordance with 31 U.S.C § 3730 and other applicable law.

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IT IS SO ORDERED this ____ day of June, 2009.

THE HONORABLE PATTI B. SARIS UNITED STATES DISTRICT JUDGE